5. 510(k) Summary

K063748

FEB - 1 2007

Submission Date	December 7, 2006
Submitter's Name and Address	Thermosurgery Technologies Inc. 2901 W. Indian School Rd Phoenix, AZ 82017
Contact Person	Gene R. Hedin Phone: 602-264-7300 Fax 602-248-3809 Email: generhedin@thermosurgery.com
Name of Medical Device	Trade Name ThermoMed Model 1.8 Common Name localized current field radio frequency instrument Classification Name: Device, Electrosurgical, Cutting and Coagulation Accessories, Class II Product Code GEI / 878.4000/Class II
Substantial Equivalence	ThermoMed Model 1.8 (K021117) Thermosurgery (K894166) ConMed Hyfrecator 2000 (K970493) Birtcher (K800617)
Device Classification	Class II
Device Description	The ThermoMed Model 1.8 is a battery-operated device that delivers precisely controlled localized current field radio frequency heat to selectively destroy certain diseased tissue.
Indications for Use	The device is intended to treat benign superficial dermatological indications that includes; warts, molluscum contagiosm, angioma, fibroma, seborrheic keratoses, acrochordon, syringoma, hydrocystoma, calvus, actinic keratoses, keloids, epidermoid cysts, cystic acne, cutaneous leishmaniasis, atypical mycobacteria, and dermatophytosis. In addition, it is intended to treat basal cell carcinoma.
Summary predicate device SE	The ThermoMed Model 1.8 for this submission is the same instrument as the ThermoMed 1.8 (K02117) currently cleared for marketing in the United States and substantially equivalent to the Thermosurgery (K894166), ConMed

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	(K970493) and the Bircher (K800617). This submission if for indications statement changes. A summary of the clinical trial performed under IDE G020145 has been included in this submission.
Safety	The device is the same as the predicate device (K02117). Clinical trial performed under IDE G020145 submitted data shows safety and effectiveness of the device.
Clinical trial summary	A single center study of 60 patients was conducted to evaluate the safety and efficacy of the ThermoMed™ Model 1.8 device in the treatment of basal cell carcinoma. Eighty five (85) percent of patients showed no evidence of tumor cells upon histological examination 3 months after a single treatment with the ThermoMed™ device. Treatment related side effects were low, with two reports of mild infection at the treatment site, one report of pain after treatment, and one report of light headedness. Patient satisfaction was high, with average patient ratings as follows: treatment comfort at 8.35, treatment convenience at 8.97, and side effects at 9.02, on a 1-10 scale with 10 being most favorable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Thermosurgery Technologies, Inc.
% Mr. Gene R. Hedin
CEO
2901 W. Indian School Road
Phoenix, Arizona 85017

FEB - 1 2007

Re: K063748
Trade/Device Name: ThermoMed Model 1.8
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 7, 2006
Received: December 19, 2006

Dear Mr. Hedin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. Indications for Use Statement

Indications for Use

510 (k) Number:

Device Name: ThermoMed Model 1.8

Indications for Use:

The device is intended to treat benign superficial dermatological indications that includes; warts, molluscum contagiosm, angioma, fibroma, seborrheic keratoses, acrochordon, syringoma, hydrocystoma, calvus, actinic keratoses, keloids, epidermoid cysts, cystic acne, cutaneous leishmaniasis, atypical mycobacteria, and dermatophytosis. In addition, it is intended to treat basal cell carcinoma.

Prescription Use _X_____ AND/OR (Part 21 CFR 801 Subpart D)

Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063748